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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,224	03/22/2001	Michael L. Boyer II	8932-226-999	2289

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EXAMINER

STEWART, ALVIN J

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 05/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/814,224

Applicant(s)

BOYER ET AL.

Examiner

Alvin J Stewart

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03/08/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 25 and 27-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25 and 27-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

Claim 26 is canceled.

### ***Claim Objections***

Claims 27-39 are objected to because of the following informalities: claims 27-39 depend on a canceled claim. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 25, 27, 29-32, 34-44 and 46-51 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al US patent 6,200,347 B1.

Anderson et al disclose an intervertebral disc (see Fig. 11B and col. 1, lines 10-11) comprising a cancellous body (73, see col. 17, lines 45-48) with first and second ends, a plurality of holes extending between the ends (see Fig. 11B), two cortical end caps (70) having receiving regions, and a plurality of cortical struts (7). The receiving regions are the plurality of holes (5), the bearing surface is the surface created at each hole along the thickness of each cortical cap and the end is the part created at the rim top surface of each hole cap.

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Regarding claim 41, it has been held that the recitation that an element is capable of performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense.

In order to be given patentable weight, a functional recitation must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language.

*In re Fuller*, 1929 C.D. 172; 388 O.G. 279.

The claims disclosed above are given their broadest reasonable interpretation. In *re* Pearson, 181 USPQ 641 (CCPA 1974).

Regarding claim 27, the struts has been entered in opening 5 by pushing the struts through the opening 5. Therefore, it has been press fitted into the opening.

Regarding claims 29 and 30, see col. 3, lines 21-23 and col. 48, lines 35-41.

Regarding claims 31 and 32, the cancellous bone is the osteoconductive material (see col. 17, lines 45-48). Natural bone promote the growth of bone tissue.

Regarding claims 36-38, see Figs. 24, 25 and 10.

Regarding claims 39 and 41, the whole structure is capable of distributing the forces exerted to the implant. It has been held that a claim is anticipated if each element of the claim is found, either expressly described or under principles of inherency, in a single prior art reference, or that the claimed invention was previously known or embodied in a single prior art device or practice. *Kalman vs. Kimberly-Clark Corp.*, 218 USPQ 789.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 28, 33, 45 and 52-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al US Patent 6,200,347 B1.

Anderson et al discloses the invention substantially as claimed. However, Anderson et al does not disclose a cap having a recess that does not extend completely through the end cap and a body having a cylindrical shape.

Anderson et al teaches in another embodiment (see Fig. 10) an implant comprising a cylindrical shape.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to change the rectangular shape to a circular shape and discloses a recess region in the cortical cap that does not extend completely through the end cap because Applicant has not disclosed that the circular shape and the recess that does not extend completely through the end cap provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the rectangular shape and the recess that does not extend completely through the end cap because the rectangular shape will promote osteoinductivity and cellularization, provides stability, mechanical strength and the holes extending completely through the end cap will keep the implant attached together.

Therefore, it would have been an obvious matter of design choice to modify the Anderson et al to obtain the invention as specified in claims 28, 33, 45 and 52-53.

***Response to Arguments***

Applicant's arguments filed 3/08/04 have been fully considered but they are not persuasive.

The new limitations entered in claims 25 and 41 still read on the previous prior art.

The first and second cortical end cap are shown in Fig. 11B (see attachment). The bearing surface has been interpreted as the surface created at each hole along the thickness of each cortical cap and the end is the part created at the rim top surface of each cap hole (see attachment). Finally, it is clearly shown in Fig. 11B that the struts bear against at least a portion of the bearing surface.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J Stewart whose telephone number is 703-305-0277. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*A. Stewart*  
Alvin Stewart  
May 19, 2004.